IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF: PAUL G. LOUBSER

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FOR: SUPERGLOTTIC AND PERI-LARYNGEAL APPARATUS FOR SUPRAGLCTTIC AIRWAY INSERTION

DECLARATION UNDER 37 CFR 1.132

PAUL G. LOUESER, M.D., the above referenced inventor, hereby declares and sayeth the following:

1. I have been practicing anesthesiology for almost 20 years, since 1984.

2 I have administered over 10,000 anesthetics.

3 In 1977, I graduated from the University of Cape Town Medical School in South Africa.

4 I completed my residency in anesthesiology at Albert Einstein College of Medicine in Bronx, New York in 1983.

5 In 1984, I completed a Fellowship in Cardiovascular Anesthesia at the Texas Heart Institute in Houston.

6. I was the Director of Anesthesiology Services at The Institute for Rehabilitation and Research in Houston, Texas from 1985 - 1992.

7. I have practiced as an attending anesthesiologist at The Methodist Hospital in Houston, Texas from 1993 to 2000.

8. I was a clinical instructor in the departments of Anesthesiology, Physical Medicine, and Rehabilitation at Baylor College of Medicine from 1985 to 1991.

9. I was an assistant professor in the department of Anesthesiology at Baylor College of Medicine from 1991 to 2000.

10. I was Director of Anesthesiology Services at The Institute for Rehabilitation and Research in Houston, Texas form 1985 to 1992.

11. I have been a member of the Quality Improvement Committee, Anesthesiology Service at The Methodist Hospital from 1993-2000.

12. I have been a Diplomate of the American Board of Anesthesiology since 1991.

13. I have been a member of the consulting staff, Department of Anesthesiology at the Veterans Administration Medical Center in Houston, Texas from 1985 to 1988.

14. I have been a medical consultant to The Texas Rehabilitation Commission since 1988.

15. I have peer-reviewed manuscripts for publication in the journals Anesthesiology and Anesthesia Analgesia, since

1999.

16. I have been President of National Cardiac Anesthesia Consultants, PA in Sugar Land, Texas since 2000.

17. I have been a senior anesthesiology consultant to Vista Staffing Solution, Inc., in Salt Lake City, Utah since 2000 and recently was appointed Medical Director.

18. I have over 30 peer-reviewed publications on anesthesiology and have presented over 100 scientific abstracts since 1984.

19. My educational background, clinical experience, and experiential base have enabled me to develop a perspective on insertion of supraglottic airway devices in the operating room. The present invention will significantly change and improve current supraglottic airway insertion practices

20. Several anatomical differences commonly manifest in patients distinguish the structures embodying my invention from the structures embodying Osborne's device. Osborne's device consists of a tube-like structure which is essential in any device intended to insufflate a patient so that medication or powder will be able to travel through the tube onto the patient's pharynx. Accordingly, Osborne's handle must also be a tube structure. Furthermore, Osborne's handle is configured

with a flattened distal tip and is interconnected with its distal shield in such a fashion to be able to spray the medication outwardly. Of course, the tube insufflator's proximal end also must open in order to be able to be attached to a Davidson syringe or rubber tube.

The proximal section of Osborne is long while the distal oval section is very short. On the contrary, in my apparatus, the distal section is at least as long as the proximal section; these two sections are preferably the same length. Osborne's curved, oval tongue depressor ("shield member") has a very short curvature length on order to not only flatten that portion of the tongue, but also to provide illumination. It is polished and curved to reflect light in an arc-like fashion onto the throat. Osborne would ostensibly use a light source such as a torch or head-light wherein shining this light source into the throat would reach the shield's surface and then reflect further into oropharyngeal structures. In order for Osborne's curved shield to effectively illuminate the oropharynx, the shield must be curved enough and short enough to display the available light in an arc-like fashion.

Osborne, in order to accomplish the task of spraying medication, must have a shield connected to the undersurface of

the tubed handle. If it were otherwise, it clearly couldn't spray medication onto the pharynx. It is this relationship that is so unique and specific that it is inconsistent with interchangeability as I contemplate for my supraglottic device. That is, the distal shield must be situated on the undersurface of the handle. The distal tip of the proximal member is obviously flattened to not only be attached to the shield, but also to facilitate spraying medication and powder. It is clear that this Osborne relationship of the proximal and distal components is quite unique.

Unlike Osborne, the handle of my device is separate from the proximal and distal components and may be interchangeable and interconnected. Indeed, it is actually difficult to know just how to hold onto an Osborne device. For instance, if medication is being injected through an Osborne device, it would presumably be in contact with saliva of the tongue, and will consequently be slimy and slippery so that stability will be in issue. My invention, on the other hand, is constructed of solid, no-tubular proximal and distal components; obviously, there is no provision or application for administration of medication or illumination. Indeed, neither of its ends is open. As explained in my patent application and illustrated in

its several tables, the proximal and distal sections are generally equal in length. On the other hand, in the Osborne device, the proximal section is typically three-to-four times longer than the distal section.

21. It is important to realize that the pharynx is divided into three components: the nasopharynx, the oropharynx, and the laryngopharynx. The nasopharynx is the region from the nasal passages to the uvula ("little tongue"); the oropharynx is the region from the uvula to the epiglottis; and the laryngopharynx is the region from the epiglottis to the vocal cords. Osborne only functions to compress the tongue in the oropharynx. It does not and, indeed, cannot be placed near the laryngopharynx. Besides being too short, Osborne's was designed to function in the oropharynx. This is evident from Osborne's discussion wherein reference is made to illuminating and spraying medication onto the tonsils which are located in the oropharynx. By contrast, my invention with its elongated distal length, is designed to automatically enter the upper laryngopharyngeal region. In addition, I designed this device to affect all three laryngeal regions ("pan-pharynx"). In so doing, my invention avoids nasopharyngeal vault impaction; it attempts to retract the tongue and to create a passage in the

oropharynx; it attempts to lift the tongue forward and to upfold the epiglottis, thereby creating space and favorable anatomic airway tube positioning in the laryngopharnyx.

22. Osborne is unable to accomplish these important functions because its structures are significantly different from my structures. Even if medication or powder were injected safely into the laryngopharynx, directly onto the vocal cords, a dangerous condition of laryngospasm may occur causing the vocal cords to slam shut and occlude the airway. Unfortunately, patients, including "pedi-patients" have died from this condition. Obviously, Osborne's is not suited for this application!

23. Consider the following critical difference between the structure-function relationship for Osborne vis á vis my invention. For a large adult, the distal section of my device should be 4-6 cm long. If Osborne were to reach the laryngopharynx and were also this length, then the proximal section would be about 12-18 cm. Practically speaking, with a proximal section this long, Osborne would protrude from the patient's mouth similar to a large pipe. The Osborne curved shield member is closer to 2 cm long. It could not be used as an illumination device if it were straight; there is no way that

it could reflect light effectively if it reached down into the laryngopharnyx.

24. The claims have been amended to clearly limit the handle member to be limited to an enclosed structure which is neither tube-like nor hollow as is the situation with Osborne. The claims have also been amended to break down the structure of the offset member into a proximal member, a distal member, and an arcuate member. Moreover, the length relationship between the proximal member and the distal member has been included to further limit the claims, and to distinguish the claimed invention over Osborne. To avoid inadvertent confusion with Osborne, references to the buccal cavity has been replaced in the claims with more specific references to the laryngopharynx.

25. For peri-laryngeal devices, I know of no other devices that have markings on them for the purposes recited in my patent application. Gomez applies to intubation of the trachea which, of course, corresponds to a wholly different airway methodology. Endotracheal tubes typically have 2 cm markings on the tube; but, the reason for such markings is to prevent the tube from going too deeply into the bronchus, i.e., causing endobronchial intubation - a very dangerous situation.

26. For these reasons I request that the examiner

reconsider his rejection of my patent application and issue an allowance.

Further declarant sayeth not.

Paul G. Loubser

Paul G. Loubser, M.D.
Applicant